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Attention: 8(e) Coordinator
U. S. Environmental Protection Agency
Document Control Officer
Office of Pollution Prevention and Toxic Substances
1200 Pennsylvania Avenue, NW
Washington, DC 20460



Ladies and Gentlemen:

Subject: Notice in accordance with Section 8(e) - Results of a Full-Scale Prenatal Developmental Toxicity Study in Wistar Rats with Diisobutylphthalate

BASF Corporation is submitting results of a prenatal developmental toxicity study in Wistar rats with Diisobutylphthalate (CAS No. 84-69-5) conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany on behalf of BASF AG, Ludwigshafen, Germany; Lonza SpA: via Enrico Fermi, N 51 I 24020 Scanzorosciate (Bergamo), Italy and Oxeno Olefinchemie GmbH, Paul-Bauman-Strasse 1, D-45764, Marl, Germany.

The study was carried out in accordance with or exceeding the requirements of the following guidelines:

- EC Commission Directive 87/302/EEC of Nov. 18, 1987, Official Journal of the European Communities, No. L 133 (1988).
- OECD Guidelines for Testing of Chemicals, Proposal for Updating Guideline 414, Prenatal Developmental Toxicity (January 2001).
- EPA, Health Effects Test Guidelines; OPPTS 870.3700: Prenatal Developmental Toxicity Study (August 1998).

The test substance was administered to 25 time-mated female Wistar rats/group as a constant homogeneous addition to the food at concentrations of 0; 1,000; 4,000 and 11,000 ppm (i.e. 0, 88, 363 or 942 mg/kg body weight/day) on day 6 through day 20 post coitum (p.c.). At scheduled necropsy, 22 - 23 females/group had implantation sites. The fetuses were assessed for external, soft tissue and/or skeletal (incl. cartilage) findings without knowledge of treatment group.

Results:

Marked signs of maternal toxicity occurred at the high concentration. These were substantiated by statistically significant impairments in food consumption and decreased absolute and corrected body weight gains.

Marginal signs of developmental toxicity occurred exclusively at 11,000 ppm (942 mg/kg body weight/day) in the form of statistically significantly reduced fetal body weights.

Although the findings are not considered to present a substantial risk to human health or the environment, BASF Corporation understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Very truly yours,

BASF CORPORATION

Edward J. Kerfoot

Edward J. Kerfoot, Ph.D.

Director, Toxicology and Product Regulations



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